K002915

JAN - 8 2001

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA-92688
(949) 713-8000

CONTACT PERSON: Anil Bhalani
Director of Regulatory Affairs and Clinical Programs

DATE OF PREPARATION: September 15, 1999

NAME OF DEVICE: Flexible Occlusion System

CLASSIFICATION NAME: Clamp, (21 CFR 878.4800) and
Clamp, Vascular (21 CFR 870.4450).

TRADE NAME: Not Determined

PREDICATE DEVICE:
1. Atraumax Surgical Clamp and Insert, K950492
Applied Medical Resources,
2. Flexible Vascular Clamp, K991589
Allegiance Healthcare Corp.

SUMMARY STATEMENT:

The Flexible Occlusion System indicated for surgical clamping during cardiovascular, peripheral vascular and general surgical procedures. The Flexible Occlusion System consists of a reusable ring handle assembly and a disposable flexible shaft with padded jaws.

The handle assembly is shaped similar to traditional clamps and is constructed of stainless steel. The function of the handle is to activate the jaws by opening and closing them. It has a ratchet designed to lock and maintain the jaws into a desired position. A mechanical linkage and connector designed at the shaft end allows for quick assembly/disassembly of the shaft and jaw assembly

The disposable shaft and jaw assembly consist of a flexible shaft with padded jaws at one end and a mechanical connector for linkage to the handle assembly at the other end. A steel cable runs through the shaft and connects the handle mechanism to the padded jaws. The shaft is made of a flexible galvanized steel coil covered with a vinyl shrink tube allowing the shaft to be curved into desired shape to access sites which are otherwise tough to reach.

The Flexible Occlusion System is substantially equivalent to the Atraumax™ or Stealth™ line of surgical clamps [510(k) K962668 and K950492]. The Applied Medical Flexible Occlusion System is substantially equivalent to predicate devices and introduces no new safety and effectiveness issues when used as instructed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Ms. Anil Bhalani
Applied Medical Resources Corporation
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

Re: K002915
Flexible Occlusion System
Regulatory Class: II (two)
Product Code: 74 DXC
Dated: November 27, 2000
Received: November 28, 2000

Dear Ms. Bhalani:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applied Medical Resources is providing this separate cover page for the Flexible Occlusion System "Indications for Use" as required.

510(k) Number: ~~Not assigned~~ K002915

Device Name: Flexible Occlusion System

Indications for Use: The Flexible Occlusion System is indicated for surgical clamping during cardiovascular, peripheral vascular and general surgical procedures.

Signature: _____ Title: *Director RA/Clinical Programs* Date: *9-15-00*

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The -Counter Use _____
(Per 21 CFR 801.109)

1-5-01 (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002915